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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,614	12/08/1999	Timothy Peter Bonnert	T1481	1165
7590	02/25/2004		EXAMINER	
Patent Department Merck & Co Inc P.O. Box 2000 Rahway, NJ 07065-0907			BRANNOCK, MICHAEL T	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/445,614	BONNERT, TIMOTHY PETER	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 December 2003.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1-3 and 7-9 is/are allowed.
- 6) Claim(s) 5 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 24 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachments(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application: Claims and Amendments***

Applicant is notified that the amendments put forth on 12/24/03, have been entered in full.

However it should be pointed out that that the amendment to claim 5, indicating the changes, fails to show that the claim has been changed to recite “SEQ ID NO: 4-11 and 13-19”, whereas prior to the amendment of 12/24/03, the claim recited “SEQ ID NO: 4-19”.

Additionally, it should be pointed out that the header on the amendment page indicated the wrong application number, i.e. 09/743,475.

### ***Response to Amendment***

#### **Withdrawn Rejections:**

The rejection of claims 1, 7-9 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No: 6444440, as set forth in the prior Office action is withdrawn for two reasons. First, it was erroneously asserted that the instant SEQ ID NO: 2 is 100% identical to 6444440-2 over the entire length of SEQ ID NO: 2; however the instant SEQ ID NO: 2 contains a glutamine residue at position 419 that is not present in 6444440-2. Additionally, the instant claim 1 requires a polynucleotide encoding the polypeptide of SEQ ID NO: 2. [emphasis added]; the polypeptide of 6444440-2 has an 127 residue extension compared to the instant SEQ ID NO: 2. Thus, for the two reasons above, the instant polypeptide of SEQ ID NO: 2 is not the same polypeptide of 6444440-2.

**Maintained Rejections:**

Claim 5 stands rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No: 6444440, which claims priority to the filing date of Application 09/132,316, see the Certificate of Correction, signed 3/11/2003.

The claims have been amended to exclude SEQ ID NO: 12, on which the prior rejection of claim 5 was based.

U.S. Patent No: 6444440 discloses a polynucleotide encoding a polypeptide (SEQ ID NO: 2) which polypeptide is 100% identical to the instant SEQ ID NO: 2 from position 420 to the C-terminal of SEQ ID NO: 2, which corresponds to position 544 of 6444440-2. The instant SEQ ID NO: 18 corresponds to a probe that would bind beginning at nucleotide position 1607 of the instant SEQ ID NO: 1 (which encodes SEQ ID NO: 2). Thus this probe would bind to the region of SEQ ID NO: 1 that encodes residues 631-637 of 6444440-2 (corresponding to residues 505-511 of the instant SEQ ID NO: 2).

U.S. Patent No: 6444440 discloses polynucleotides encoding various fragments of 6444440-2 that are useful for carrying-out the invention, particularly a nucleic acid consisting of a polynucleotide that encodes residues 626-652 of 6444440-2 is disclosed (see col 8, particularly lines 8 and 30). Such a polynucleotide would comprise an oligomer containing the instant SEQ ID NO: 18 and would not differ from a polynucleotide encoding a polypeptide of the instant SEQ ID NO: 2 because SEQ ID NO: 2 and 6444440-2 are identical to each other at these positions.

Applicant's arguments, as they may relate to the instant rejection are addressed below.

Applicant argues that it is doubtful that one skilled in the art would be able to practice the invention as claimed in the prior patent, because the specific temperature of 55 degrees is not taught. This argument has been fully considered but not deemed persuasive for two reasons. The 6444440 patent teaches that the channel is activated by heat, thus the skilled artisan would know to raise the temperature until the channels open, absent evidence to the contrary. Second, the issue is moot because claim 5 requires no activity; The 6444440 patent teaches how to make the claimed probe.

Applicant argues that the 6444440 patent erroneously incorporates 127 residues translated from the 5'-untranslated region on to the N-terminus of the protein, and thus the protein would not be expected to function. Applicant's arguments regarding the assertion that the 127 residues are erroneous is more likely true than not. However, absent some evidence to the contrary, the skilled artisan would think it more likely than not that the extra residues would not interfere with the function because the use of large N-terminal extensions on proteins is standard in the art, e.g. green fluorescent protein, B-gal, and many other reports, as is well appreciated in the art. Further, Applicant's arguments are not persuasive regarding the concept of a frame shift due to the presence of insertions in the 5'-untranslated region. The 6444440 patent teaches the same reading frame as the instant specification.

***Allowable Subject Matter***

Claims 1-3 and 7-9 are allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

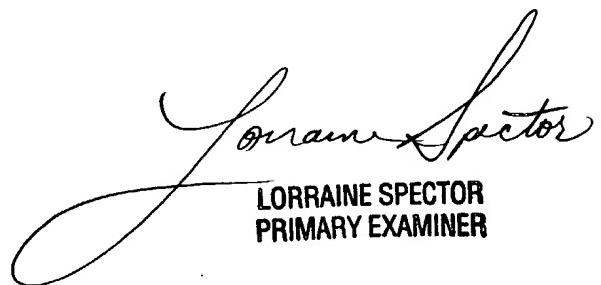
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (571) 272-0871.

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Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Lorraine Spector  
LORRAINE SPECTOR  
PRIMARY EXAMINER

MB



February 23, 2004